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UNITED STATES DEPARTMENT OF COMMERCE

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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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U.S. PATENT OPERATIONS/ONE
M/S 10-1-B-431
ANGEN INC.
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HM21/0303

EXAMINER

HAYES, R

ART UNIT

PAPER NUMBER

DATE MAILED:

08/03/98

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

08/182183

Applicant(s)

Lin J al

Examiner

Vayer

Group Art Unit

1645

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Response

A SHORTENED STATUTORY PERIOD FOR RESPONSE IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a response be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for response is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to respond within the set or extended period for response will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 5/8/98
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 88-92, 94, 117-177 is/are pending in the application.
- ☐ Of the above claim(s) _____ is/are withdrawn from consideration.
- ☒ Claim(s) 118-119, 124, 152, 165-171 is/are allowed.
- ☒ Claim(s) 88-90, 92, 94, 117, 120-123, 125-151, 153-164, 172-174, 177 is/are rejected.
- ☒ Claim(s) 91, 175-176 is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____.

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____ ☐ Interview Summary, PTO-413
- ☐ Notice of References Cited, PTO-892 ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948 ☐ Other _____

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DETAILED ACTION

✓ 1. Since this application is eligible for the transitional procedure of 37 CFR 1.129(a), and the fee set forth in 37 CFR 1.17(r) has been timely paid, the finality of the previous Office action is hereby withdrawn pursuant to 37 CFR 1.129(a). Applicant's second submission after final filed on 5/08/98 has been entered.

✓ 2. The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1645.

✓ 3. The rejection of claims 124 & 136-142 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification, is withdrawn due to Applicants' arguments, or due to the amendment of the claims.

✓ 4. The rejection of claims 117, 121 & 124-125 under 35 U.S.C. 112, second paragraph, as being indefinite, is withdrawn due to the amendment to the claims.

✓ 5. Claims 118-119, 124, 152 & 165-171 are allowed.

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6. Claims 91, 175 & 176 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

✓ 7. Applicant's arguments filed 5/08/98 have been fully considered but they are not deemed to be persuasive.

✓ 8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

9. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 90, 92, 127-128, 133-134, 138, 140-142, 144 & 159-161 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. For example, the current recitation of "A host cell" encompasses a human organism. It is suggested that amending the claims to "an isolated host cell" should obviate this rejection. For example, claims 159 & 160 would then be allowable. It is also suggested that amending claim 90, for example, to "the isolated [a] nucleic acid [sequence according to] of claim 88" would more clearly define the invention, in that cells are transformed with molecules, not sequences. It should also be

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noted that claim amendments directed to *in vivo* hosts/gene therapy will be withdrawn, as being drawn to an non-elected invention.

10. Claims 88-90, 92, 94, 117, 121-123, 125-134, 143-149, 151 & 158 are again rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons made of record and as follows.

Claims 88, 122 & 151 recite "further comprising a codon encoding an amino-terminal methionine residue." Applicants argue on page 14 of the response that "an amino-terminal methionine residue" is described on page 19 of the specification. In contrast to Applicants' assertions, "an amino-terminal methionine residue" is contemplated for *only* "bacterial expression systems", versus the broader scope now claimed that encompasses eukaryotic "expression systems"; thereby, constituting new matter.

Claims 117, 121 & 125 now recite "50⁰ C or 42⁰ C, respectively, followed by washing ...at room temperature". In contrast, the specification in Example 6 discloses "*washing at 50⁰ C*" after hybridizing overnight at 50⁰C (i.e., pg. 58; as it relates to the molecule depicted in SEQ ID NO:10), whereas the hybridization conditions at 42⁰C overnight require inclusion of "30% *formamide*" (i.e., pg. 63; as it relates to the different molecule depicted in SEQ ID NO:14). In other words, Applicants now decrease the stringency contemplated in the specification, and also

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change the scope of those sequences used during the hybridization conditions described (i.e., as it relates to probe size, GC content and resulting melting temperatures); thereby, constituting new matter. Additionally, the specification does not appear to contemplate sequences that "differ in codon sequence due to the degeneracy of the genetic code" that *also* hybridize to such, or that are initially "70% identical to" named sequences, which broadens the scope contemplated within the specification; thereby, constituting new matter.

11. Claims 117, 120, 122-123, 125-151, 153-158, 161-164, 172-174 & 177 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation of a "% identity" is indefinite, for the reasons made of record in paper # 25, and as follows. In particular, it is not known what is envisioned to meet this limitation, since the algorithm used to calculate the percent identity, or those parameters (e.g., gap penalties, mismatch penalties) required to determine such, remains not disclosed within the specification. For example, the "incorporation by reference" by Dayoff now inserted into the specification only describes that "two related proteins may be aligned with the insertion of an average of 3 or 4 gaps in a length of 100 residues", versus whether identical size molecules are being compared, or how gaps, for example, created by alternative splicing, are to be used in the calculation. For example, are alternatively spliced exons treated as mismatches over the full length of the sequence, or are common amino acid residues considered; for example, 100% identity with their corresponding

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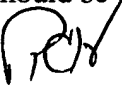
amino acid residues? In other words, it is unknown by this limited disclosure from Dayoff what algorithm is to be used for calculating "% identity", or how "gap penalties", etc., are to be factored into the calculation, or what default settings for those other parameters required for calculating "% identity" should be used (i.e., as it relates to the example made of record in paper #25). Additionally, different sequences contain different numbers of amino acid residues (i.e., including additions, substitutions, deletions & truncations), and it remains unclear how such differences in the numbers of amino acid residues are to be treated, as it relates to calculating a "% identity" in "a length of 100 residues", when few amino acid sequences are exactly 100 residues in length.


Claims 117 & 125 are also indefinite because molecules "in excess of 70% identity" that then "differ in codon sequence due to degeneracy of the genetic code" would result in molecules with less than 70% identity, thereby, being contradictory to the claim language in "(b)".

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (703) 305-3132. The examiner can normally be reached on Monday through Thursday, and alternate Fridays, from 8:30 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell, can be reached on (703) 308-4310. The fax phone number for this Group is (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.


Robert C. Hayes, Ph.D.
July 15, 1998


PAULA K. HUTZELL
SUPERVISORY PATENT EXAMINER